General

Guideline Title

The Society of Thoracic Surgeons 2017 clinical practice guidelines for the surgical treatment of atrial fibrillation.

Bibliographic Source(s)

Badhwar V, Rankin JS, Damiano RJ Jr, Gillinov AM, Bakaeen FG, Edgerton JR, Philpott JM, McCarthy PM, Bolling SF, Roberts HG, Thourani VH, Suri RM, Shemin RJ, Firestone S, Ad N. The Society of Thoracic Surgeons 2017 clinical practice guidelines for the surgical treatment of atrial fibrillation. Ann Thorac Surg. 2017 Jan;103(1):329-41. [126 references] PubMed

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Recommendations

Major Recommendations

Definitions for the class of recommendations (I, IIA, IIB, III) and levels of the evidence (A-C) are provided at the end of the "Major Recommendations" field.

Mitral Valve Operations and Concomitant Surgical Ablation

Surgical ablation for atrial fibrillation (AF) can be performed without additional risk of operative mortality or major morbidity, and is recommended at the time of concomitant mitral operations to restore sinus rhythm. (Class I, Level A)

Aortic Valve and Coronary Artery Bypass Grafting (CABG) Operations with Concomitant Ablation

Surgical ablation for AF can be performed without additional risk of operative mortality or major morbidity, and is recommended at the time of concomitant isolated aortic valve replacement (AVR), isolated CABG, and AVR plus CABG operations to restore sinus rhythm. (Class I, Level B nonrandomized)

Stand-Alone Surgical Ablation for AF

Surgical ablation for symptomatic AF in the absence of structural heart disease that is refractory to class I/III antiarrhythmic drugs or catheter-based therapy is reasonable as a primary stand-alone procedure to restore sinus rhythm. (Class IIA, Level B randomized)

Surgical ablation for symptomatic persistent or long-standing persistent AF in the absence of structural heart disease is reasonable as a stand-alone procedure using the Cox-Maze III/IV lesion set compared with pulmonary vein isolation (PVI) alone. (Class IIA, Level B nonrandomized)

Surgical ablation for symptomatic AF in the setting of left atrial enlargement (≥4.5 cm) or more than moderate mitral regurgitation by PVI alone is not recommended. (Class III no benefit, Level C expert opinion)

Additional Considerations for Surgical Ablation Therapy

It is reasonable to perform left atrial (LA) appendage excision or exclusion in conjunction with surgical ablation for AF for longitudinal thromboembolic morbidity prevention. (Class IIA, Level C limited data)

At the time of concomitant cardiac operations in patients with AF, it is reasonable to surgically manage the LA appendage for longitudinal thromboembolic morbidity prevention (Class IIA, Level C expert opinion).

Multidisciplinary heart team assessment, treatment planning, and long-term follow-up can be useful and beneficial to optimize outcomes of surgical ablation for AF. (Class IIA, Level C expert opinion).

Definitions

Classification of Strength of Recommendation

Class I (strong; benefit >>> risk): procedure is useful, effective, and beneficial. Recommendation: procedure should be performed.

Class IIA (moderate; benefit >> risk): procedure can be useful, effective, and beneficial. Recommendation: procedure is reasonable.

Class IIB (weak; benefit equal to or greater than risk): effectiveness is unknown, unclear, or uncertain. Recommendation: procedure might be reasonable.

Class III, no benefit (moderate; benefit equals risk): procedure is not useful, effective, or beneficial. Recommendation: procedure should not be performed.

Class III, harm (strong; benefit less than risk): Procedure potentially causes harm or excess mortality and morbidity. Recommendation: procedure should not be performed.

Level of Quality of Evidence

Level A: high-quality evidence from more than one randomized controlled trial (RCT); meta-analyses or high-quality RCTs; or one or more RCTs corroborated by high-quality registry studies.

Level B randomized: moderate quality evidence from one or more RCTs or meta-analyses of moderate quality.

Level B nonrandomized: moderate quality of evidence from one or more well-designed, well-executed nonrandomized studies, registries, or observational analyses; meta-analyses of such studies.

Level C limited data: randomized or nonrandomized observational or registry studies with limitations of design or execution; meta-analyses of such studies; mechanistic or physiologic investigation in human subjects.

Level C expert opinion: consensus of expert opinion based on clinical experience.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Atrial fibrillation

Guideline Category

Management

Treatment

Clinical Specialty

Cardiology

Internal Medicine

Thoracic Surgery

Intended Users

Advanced Practice Nurses

Hospitals

Nurses

Physician Assistants

Physicians

Guideline Objective(s)

- To present a balanced review of current knowledge in the area of surgical ablation
- To provide evidence-based recommendations for clinical practice
- To potentially improve and optimize future patient outcomes
- To assess the safety of performing surgical ablation as a concomitant or principal procedure, defined by mortality or major morbidity, for three surgical approaches: primary atriotomy operations, primary nonatriotomy operations, and stand-alone operations
- To provide a summary assessment of efficacy regarding quality of life and rhythm endpoints as measured by multiple-society monitoring standards

Target Population

Patients undergoing surgical ablation for atrial fibrillation

Interventions and Practices Considered

1. Concomitant surgical ablation associated with primarily open atrial operations (i.e., mitral valve repair or replacement [MVRR])
2. Concomitant surgical ablation at the time of primary closed atrial operations (i.e., aortic valve replacement [AVR], coronary artery bypass grafting [CABG], or AVR plus CABG)
3. Surgical ablation performed as a stand-alone operative procedure
4. Additional considerations for surgical ablation therapy

Major Outcomes Considered

- Arrhythmia conversion to sinus rhythm
- All-cause operative or late mortality
- Major morbidity (prolonged ventilation, deep sternal infection, permanent stroke, renal failure, reoperation)
- Recurrence (defined as any atrial tachyarrhythmia lasting longer than 30 seconds on a 24-hour Holter monitor recording 6 months after surgical ablation)

- Quality of life

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Searches of Patient Registry Data

Description of Methods Used to Collect/Select the Evidence

Literature Review

Literature searches focused on randomized controlled trials (RCTs) and meta-analyses, but also used registries, observational and descriptive studies, reviews, and expert opinion. Emphasis was placed on evidence that was relevant to important clinical questions.

Searches were accomplished in the Medline and EMBASE databases. Formal search results were limited to papers published on human subjects in English after January 1, 2004. The end date for the search was October 2015. The following search terms were used to identify relevant studies: exp Atrial Fibrillation, afib.mp, atrial fibrillation.mp, AF.mp, Surgical adj4 ablation.mp, cyroablation.mp, Ablation Techniques, Radiofrequency adj4 ablation.mp, Cox MAZE or Cox-MAZE.mp, RFA.mp, exp Microwaves, mortality.mp. or exp Mortality, exp Survival/ or Survival.mp, exp Stroke/ or Stroke.mp, Hemorrhage.mp. or exp Hemorrhage, bleeding.mp, heart failure.mp. or exp Heart Failure, exp Patient Readmission, readmission.mp, Heart Block.mp. or exp Heart Block, Reintervention.mp, exp Treatment outcome, exp Treatment failure, exp Recurrence, exp "Quality of Life", exp Reoperation, and exp Pacemaker, Artificial.

The literature search was supplemented by manual examination of the identified studies. Abstracts were reviewed by at least three persons for relevance. A total of 1511 results were obtained, and papers were excluded if they were case reports, were population-based studies covering incidence and risk factors for atrial fibrillation (AF), had a primary focus on nonsurgical procedures, or sought to identify potential outcomes or markers not within the focus of the guideline. The remaining 156 relevant articles were analyzed in detail by the writing group, and recommendations were reviewed and formulated by all members consistent with Institute of Medicine standards for guideline development.

Number of Source Documents

A total of 156 relevant articles were analyzed in detail.

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Level of Quality of Evidence

Level A: high-quality evidence from more than one randomized controlled trial (RCT); meta-analyses or high-quality RCTs; or one or more RCTs corroborated by high-quality registry studies.

Level B randomized: moderate quality evidence from one or more RCTs or meta-analyses of moderate quality.

Level B nonrandomized: moderate quality of evidence from one or more well-designed, well-executed nonrandomized studies, registries, or

observational analyses; meta-analyses of such studies.

Level C limited data: randomized or nonrandomized observational or registry studies with limitations of design or execution; meta-analyses of such studies; mechanistic or physiologic investigation in human subjects.

Level C expert opinion: consensus of expert opinion based on clinical experience.

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Observational studies were appraised using the Newcastle-Ottawa scale. Appraisals of randomized controlled trials (RCTs) and meta-analyses utilized checklists modeled after those recommended by the Center on Evidence Based Medicine, and all extracted and reviewed data were compiled in the form of evidence tables by three coauthors (see Appendices 2–4 [see the "Availability of Companion Documents" field]).

Critical Appraisal

The class of recommendation is considered an estimate of the size of the treatment effect, balancing risks versus benefits, and whether a given treatment is or is not useful and effective (see the "Rating Scheme for the Strength of the Recommendations" field). The level of evidence is an estimate of the certainty or precision of the treatment effect (see the "Rating Scheme for the Strength of the Evidence" field).

Methods Used to Formulate the Recommendations

Expert Consensus (Delphi)

Description of Methods Used to Formulate the Recommendations

The Society of Thoracic Surgeons (STS) Workforce on Evidence Based Surgery assembled a task force in 2015 to address recommendations for surgical ablation for atrial fibrillation (AF). The guideline writing committee reviewed the literature and assessed the quality of evidence relative to operation type. Operations were classified as concomitant surgical ablation (SA) associated with primarily open atrial operations (i.e., mitral valve repair or replacement [MVRR]), concomitant SA at the time of primary closed atrial operations (i.e., aortic valve replacement [AVR], coronary artery bypass grafting [CABG], or AVR plus CABG), and SA performed as a stand-alone operative procedure.

Guideline generation was sponsored by the STS without commercial support, and formulated by a volunteer member writing committee. A balanced unbiased writing group was assembled, emphasizing both clinical experience and scientific background. The available literature was analyzed in detail by the writing group. Consensus was reached using Delphi methodology to formulate recommendations consistent with Institute of Medicine standards for guideline development. Unanimous consensus was achieved by all writing committee members on the general content, class of recommendations (COR) and level of evidence (LOE) for each recommendation (see Appendix 1 [see the Availability of Companion Documents]).

Rating Scheme for the Strength of the Recommendations

Classification of Strength of Recommendation

Class I (strong; benefit >>> risk): procedure is useful, effective, and beneficial. Recommendation: procedure should be performed.

Class IIA (moderate; benefit >> risk): procedure can be useful, effective, and beneficial. Recommendation: procedure is reasonable.

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Class III, harm (strong; benefit less than risk): Procedure potentially causes harm or excess mortality and morbidity. Recommendation: procedure should not be performed.

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

Internal Peer Review

Description of Method of Guideline Validation

The manuscript was presented to and approved by the Workforce on Evidence Based Surgery and the Society of Thoracic Surgeons (STS) Executive Committee.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

The guideline is based on randomized controlled trials (RCT) and meta-analyses, but also used registries, observational and descriptive studies, reviews, and expert opinion.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

It is clear that surgical ablation is effective in reducing atrial fibrillation (AF) and improving quality of life. It is possible that data from continued longitudinal follow-up of larger patient cohorts will further illuminate the survival benefit of surgical ablation. Given that surgical ablation can currently be applied without increase in operative risk of mortality or major morbidity, and that benefits to long-term rhythm control and quality of life appear consistent, the more frequent performance of guideline-directed surgical ablation may improve patient outcomes.

Potential Harms

Operative Safety of Surgical Ablation in Mitral Patients

Using multivariable regression and propensity matching, a Society of Thoracic Surgeons (STS) database registry study demonstrated safety of surgical ablation concomitant to mitral surgery in a cohort made up of 52% mitral patients. Patients who underwent surgical ablation, however, had a 26% greater likelihood of requiring a permanent pacemaker (risk adjusted odds ratio 1.26, 95% confidence interval: 1.07 to 1.49, $p = 0.007$). In a recent randomized trial of mitral valve surgery patients, the authors reported no increase in major operative risk with surgical ablation, but a twofold to threefold higher incidence of pacemaker implantation among patients undergoing ablation versus patients undergoing mitral valve surgery alone. The largest meta-analyses, which included any concomitant operation, however, reported no significant difference in permanent pacemaker implantation. Although influences on nonfatal complications are controversial, it is clear that concomitant ablation has not significantly increased risk of death or major complications.

Operative Safety of Aortic Valve Replacement (AVR) or Coronary Artery Bypass Grafting (CABG), or Both, with Surgical Ablation

A recent matched cohort analysis compared 124 patients from a single institution who underwent AVR with or without a concomitant maze procedure. No significant differences were observed in operative mortality and morbidity. Another cohort study of 124 patients also reported no significant difference in mortality and morbidity associated with AVR with or without CABG and concomitant surgical ablation. A 2014 randomized study compared both CABG plus a Cox maze procedure and CABG with pulmonary vein isolation (PVI) to CABG alone and reported no in-hospital mortality.

Operative Safety of Stand-Alone Surgical Ablation

In a 2013 systematic review that compiled results from 23 observational studies with 752 patients who underwent minimally invasive stand-alone procedures, operative mortality was 0.4%. Complication rates attributed to surgery were just 3.2%. Analysis of stand-alone procedures recorded in the STS National Database showed an operative mortality rate of 0.74%. The complication rate was considerably higher at 16.43%, although major morbidities such as stroke (0.72%), renal failure (2.45%), and bleeding (0.99%) were low. Pacemakers were implanted in 1.03% of patients.

Qualifying Statements

Qualifying Statements

Limitations of Studies

- Several of the investigations classified as high-quality evidence documenting the safety endpoint of concomitant surgical ablation (SA) for atrial fibrillation (AF) at the time of primary mitral operations include occasional patients receiving additional secondary operative procedures. Although the majority of populations defined are weighted to persistent or longstanding persistent (nonparoxysmal) AF, occasional studies include mixed populations of paroxysmal AF patients, lending a degree of heterogeneity to the study populations. Finally, selection biases may be inherent to retrospective data that caution interpretation of such studies.
- The majority of evidence documenting the safety endpoint and rhythm efficacy endpoint of concomitant SA for primarily closed atrial procedures (isolated aortic valve replacement [AVR], coronary artery bypass grafting [CABG], or AVR plus CABG) include patients receiving additional secondary operative procedures. Whereas the majority of populations defined are weighted to paroxysmal AF, many include persistent or longstanding persistent nonparoxysmal AF, lending a degree of inhomogeneity to the study populations.
- The majority of the studies comprising the evidence documenting the safety endpoint and rhythm efficacy endpoint of stand-alone SA for AF are of moderate quality as they include a variety of lesion sets and energy sources leading to technique variability. Although the majority of defined populations are weighted to paroxysmal AF, many include persistent or longstanding persistent (nonparoxysmal) AF, lending a degree of heterogeneity to the study populations.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

IOM Domain

Effectiveness

Safety

Identifying Information and Availability

Bibliographic Source(s)

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Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2017 Jan

Guideline Developer(s)

Society of Thoracic Surgeons - Medical Specialty Society

Source(s) of Funding

Guideline generation was sponsored by the Society of Thoracic Surgeons without commercial support.

Guideline Committee

Society of Thoracic Surgeons Workforce on Evidence Based Surgery

Surgical Treatment of Atrial Fibrillation Guidelines Writing Group

Composition of Group That Authored the Guideline

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Financial Disclosures/Conflicts of Interest

Efforts were made to avoid all conflicts of interest due to industry relationships, and all committee members disclosed current industry associations.

Drs Damiano and Gillinov disclose a financial relationship with AtriCure and Medtronic; Drs Rankin and Philpott with AtriCure; Dr Roberts with Medtronic; Dr Ad with AtriCure, Medtronic, and Liva Nova Inc.

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

Available from the Society of Thoracic Surgeons Web site .

Availability of Companion Documents

Supplementary Appendices 1-4 can be viewed in the online version of the original guideline document available from the Annals of Thoracic Surgery Web site .

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI Institute on April 21, 2017.

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